MEMORANDUM

DATE: March 21, 2001

TO: Division of Shellfish Sanitation Staff

FROM: Robert E. Croonenberghs, Ph.D., Director
Division of Shellfish Sanitation

THROUGH: Robert W. Hicks, Director
Office of Environmental Services

SUBJECT: Plants – Procedure - HACCP Certification Requirements for Shellfish Plants

Delete Working Memo #S- 272

Purpose

The objectives of this protocol are:

1. To establish a uniform certification procedure for shellfish plants.
2. To establish a minimally acceptable HACCP plan by which to evaluate industry HACCP plans.

Introduction

The National Shellfish Sanitation Program Model Ordinance (MO) requires that all shellfish plants have a proper HACCP plan in order to be certified for the upcoming certification cycle. This memo will outline how these certifications will take place and how compliance with the MO will be judged.

Minimally Acceptable HACCP Plan

The ver. 3/20/01 HACCP plans attached are the minimally acceptable HACCP plans the Division will use to evaluate shellfish dealers for certification. Shellfish dealers can have critical control points (CCPs) and critical limits (CLs) that are more stringent, but not less than those stated in the attachments, unless the dealer can prove through a hazard analysis that a CCP or CL can be changed. The central office must approve any proposed changes to a CCP or CL. The plans do not represent the desires of the Division of Shellfish Sanitation, but rather contain the requirements of the MO and additional requirements from FDA in their 2/1/00 Guidance Document #1. HACCP plans are supposed to be living documents that change as science and practice validate other ways of eliminating hazards from occurring. Shellfish specialists will have to evaluate future plans based upon the requirements in the MO which define CCPs and critical limits. These requirements can change from year to year. Therefore, at the beginning of each certification cycle, HACCP plans shall be evaluated based upon the latest MO.

Certification Procedures

1. In order to be certified all dealers must have a suitable HACCP plan. This means that they must have all of the necessary forms prepared, with equipment, trained personnel and other necessary items in place.

2. All shellfish plants must have performed a hazard analysis. They are not required to show you their hazard analysis, but they must demonstrate knowledge of their plan and how it was developed. It must be stressed that they be aware of all elements of their plans and what their HACCP certified reviewer will do.

3. In order to be certified and listed in the November Interstate Certified Shellfish Shippers List, certification forms must be returned to the Central Office by the end of the first week of October. The inspection form must indicate that the plant has a minimally acceptable HACCP plan and that they have the appropriate sanitation monitoring procedures (Chapter X .02 in the MO) in place and that the facilities have no structural or functional problems which are out of compliance with the MO requirements.

General Items to check on all HACCP plans

- Whether the dealer's process changed from the last HACCP plan
- Whether the title of people that are indicated by the HACCP plan to monitor are the ones actually writing down the record, or use a generic statement of "plant personnel as assigned"
- Whether the plan is signed and dated every year
- Monitoring forms
    - Whether the firm has copies of all types of monitoring forms they will need
    - Whether the name and address of the firm is on these forms
    - Whether the actual times of actions are recorded, as opposed to the use of check marks
    - Whether the type of record the firm is keeping matches what the plan says will be measured

Specific Guidance Concerning Shellfish HACCP Plans
(note that shellfish refers to both shellstock and shucked shellfish for this section)

Receiving shellfish

- Must include the words "pathogens, marine biotoxins and toxic chemicals"
- Buying shellstock from other harvesters or dealers is beyond the scope of a boat certification, since storage would be required on occasion.

Shellstock - Points of transfer/loading docks

- This requirement has been put in the MO and FDA has debited us for not having it.
- Two hours out of temperature control is the requirement. The logic for a shorter time period for shellstock than for shucked product is that shucked product must be chilled to 45° F by the end of the time period, whereas shellstock is merely put under refrigeration and takes longer to cool.

Shellstock - Washing, grading and packing

- This CCP is not stated in the MO, but the requirement stands that once under refrigeration, shellstock must not be taken out of refrigeration. We are assuming, and FDA concurs, that 2 hours for processing in addition to the CCP for time at loading docks is reasonable. However, this CCP and the one for loading docks cannot be combined into 4 hours and monitored for one 4 hour period, because total time at loading docks is limited to 2 hours. One form to record times out of temperature at the CCPs for both loading docks and grading can be used, but the total time for each CCP is limited to 2 hours apiece. The rationale for this is that loading docks can be much hotter than grading rooms, and the shellstock should not be exposed to these high temperatures for more than 2 hours.
- DSS interpretation for washing, grading and boxing
    - Since dealers have 20 hours to get shellstock harvested under refrigeration, if they wash, bag and tag the product the day of harvest, then they do not need a CCP for it. Dealers must indicate in their hazard analysis that this is what they are doing and therefore do not need the CCP.
- DSS interpretation for shipments from dealer to dealer on day of harvest
    - Shellstock shipped from dealer to dealer on the day of harvest does not have to be refrigerated, since it falls within the exception from the refrigeration requirement within 20 hours of harvest.

Shellfish storage

- Shellfish under refrigeration storage must be monitored a minimum of twice per day, this is FDA's required guidance to its shellfish specialists.
    - Shellstock under refrigerated storage must have the corrective actions worded exactly as provided if only monitored twice per day.
- Iced shellfish must be monitored a minimum of once per day and corrective actions *should* be included to reflect the essence of what is provided.

Frequency of temperature sensor calibration

- FDA is teaching that monthly calibration is required, it is not acceptable for a HACCP trained individual to establish a longer calibration frequency.
- Monthly calibration can be avoided if all of the following are true:
    - The thermometer is certified with an expiration date to be NIST traceable for a certain period of time
    - That time interval is current
    - The thermometer has identification on it to identify it to the certificate, such as a serial number.
- Many thermometers are sold as NIST traceable, but are not acceptable since they are only certified to be traceable at the time of manufacture and not for a certain period of time.

Shucking and packing shellfish

- Six hour processing time
    - The Division still maintains that a 6 hour processing time is acceptable, though the MO only allows 4 hours and the FDA downgraded our plants in 2000 for using it.

- The data we developed is being statistically evaluated by Va. Tech now (prior to FDA's next evaluation).
- If the data shows 6 hours is unacceptable, we will have to immediately require a 4 hour interval to avoid a "major nonconformity" with the ISSC and the FDA.

- recording processing time
  - plant owners may develop a number of different ways to record this information
  - be sure that whatever an owner develops, that the plant can actually function within the parameters set and consistently meet the critical limits of time and temperature
  - one way to ease the record keeping is as follows
    - write a standard operating procedure (SOP) for packing shellfish
      - receiving window
        - record delivery time of shucker
        - establish that when shucked product is delivered to the receiving skimmer, that upon skimming into the temporary holding container that it is immediately and thoroughly packed in layers of ice and stirred, this stops the clock for the time out of temperature control used by the picker
        - hourly measure and record the temperature of this container to prove that it is chilled
        - ensure that shucker's processing time plus the standard packing time does not exceed allowed total processing time
      - blowing and packing
        - begin blowing with iced shucked oysters
        - use timer on each blower tank, and end blowing when timer rings
        - establish that as soon as blowing ends, that sufficient ice will be added to the blower tank and mixed in to ensure cooling to <45° F
        - record temperature of tank
        - write the SOP to use the amount of time while blowing as the time out of temperature control
      - using this method, oysters from each shucker do not have to be tracked through the blowing process, because the blowing process time has been standardized
      - verify process annually in writing as part of the hazard analysis justifying the critical limit for shucking time

- Interim repacking of shucked shellfish (shucked and stored in the cooler in large containers prior to final packing)
  - The HACCP plan must address this step.
  - The time out of temperature control is cumulative within the 6 hours processing time. No extra time can be provided for this step.
  - The dealer could eliminate the monitoring at this step if he does a verification study to show that the temperature of the shucked shellfish does not exceed 45° F during his standard process.

Repacking shucked shellfish

- The MO currently requires shellfish not to exceed 45° F during repacking.
- It is quite possible that the ISSC will allow 2 hours out of temperature control this summer.
- DSS interpretation - if a plant must raise the shellfish above 45° F during repacking, then we will accept a maximum of 2 hours out of temperature control for now

Miscellaneous points

Verification studies:

- Must be written to specifically say how they address the hazard and what CCP or monitoring step they are eliminating
- Must be added to the HACCP plan
- Must be done yearly
- If a dealer is found to repeat not to complying with his verification study, then he will have to implement monitoring the CCP.

Compliance, when evaluating records, means whether there are no more than 10% of the records missing or improper.

Example HACCP Plan Form - Repacker

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Repacking of previously packed

_____ shellfish for fresh distribution.

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Receiving	Shellfish may contain pathogens, marine biotoxins and toxic chemicals if received from growing waters closed to shellfish harvesting.	1) Receive only shellstock obtained from licensed harvester or aquaculturist who has; a) harvested the shellstock from approved areas as indicated by the tag and b) identified the shellstock with a tag or transaction record -or- 2) Receive shellstock or shucked shellfish obtained from a dealer who has identified the shellfish with a tag, transaction record or label.	Shellfish tag, label or transaction record	Visual check	Upon receipt of each shipment	Plant personnel as assigned	Reject any shellfish that are without an identifying tag, label or transaction record.	Minimum weekly review of shellfish receiving records and corrective action records by a HACCP trained individual.	Receiving Record Corrective action record

Signature of Company Official: _____ Date: _____ Page # 1

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Repacking Shucked shellfish	Growth of pathogenic bacteria	Shucked shellfish shall be maintained at an internal temperature of 45° F (7.2° C) or less. Frozen shellfish thawed for repacking shall not exceed an internal temperature of 45° F (7.2° C).	Temperature of shucked shellfish during processing.	Check temperature of representative sample of shellfish.	1) At least every 2 hours during processing; or 2) At the end of the repacking operation if less than 2 hours.	Plant personnel as assigned	1) Add ice to containers or vessels of 128 oz. (1 gallon) or greater containing the shellfish to be repacked. 2) Chill containers of less than 128 oz. (1 gallon) as rapidly as possible with ice. 3) Hold shellfish aside and evaluate by, at a minimum, a HACCP trained individual.	Minimum weekly review of shellfish repacking records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shucked shellfish repacking record Thermometer calibration record Corrective action record

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			(4) What	(5) How	(6) Frequency	(7) Who			
Shucked meat storage	Growth of pathogenic bacteria	Shucked and packed shellfish must be stored in: a) Ice or b) Under refrigeration at a temperature of 45°F (7.2°C) or less.	a) Presence of adequate ice or b) Storage area temperatures.	a) Visual check for presence of adequate ice or b) Recording storage area temperatures.	a) Minimum of 1 time per day for iced product or b) Minimum of 2 times per day for refrigerated product.	Plant personnel as assigned.	If iced shellfish are without adequate ice, or if shellfish are not iced and cooler temp. is above 45°F, take temperature of shellfish. Shucked shellfish with a temperature greater than 45°F are iced and held for evaluation by, at a minimum, a HACCP trained individual for final disposition. Restore temperature control.	Minimum weekly review of shucked meat storage records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shucked meat storage record Thermometer calibration record Corrective action record

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			(4) What	(5) How	(6) Frequency	(7) Who			
Shellstock Points of transfer/loading dock	Growth of pathogenic bacteria	Once under temperature control, shellstock not permitted to remain outside of refrigeration for more than 2 hours at loading dock.	Time out of temperature control.	Record duration of time shellstock outside of temperature control.	For every lot or pallet.	Plant personnel as assigned.	If the shellstock are out of temperature control for more than 2 hours then check internal temperature. If the internal temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to a cooler. If the shellstock temperature is >50°F, the product will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated by a HACCP trained individual to insure the product is safe.	Minimum weekly review of shellstock transfer records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock temperature control record Thermometer calibration record Corrective action record

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			(4) What	(5) How	(6) Frequency	(7) Who			
Shellstock Washing, grading and packing	Growth of pathogenic bacteria	Once under temperature control, shellstock not permitted to remain outside of refrigeration for more than 2 hours while processing.	Time out of temperature control.	Record duration of time shellstock outside of temperature control.	For every lot or pallet.	Plant personnel as assigned.	If the shellstock are out of temperature control for more than 2 hours then check internal temperature. If the internal temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to a cooler. If the shellstock temperature is >50°F, the product will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated by a HACCP trained individual to insure the product is safe.	Minimum weekly review of shellstock transfer records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock temperature control record Thermometer calibration record Corrective action record

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Shellstock storage	Growth of pathogenic bacteria	Shellstock must be: a) Iced; or b) Stored in a storage area or conveyance maintained at 45°F (7.2°C) or less; or c) Placed in an approved wet storage area.	a) Presence of ice; or b) Shellstock cooler temperature; or c) Wet storage area water quality	a) Visual check for presence of adequate ice; or b) Record shellstock cooler temperatures; or c) Wet storage permit	a & b) Minimum of 2 times per day	Plant personnel as assigned	(Note: If monitoring frequency is less than 3 times/day, the following corrective actions must be listed for cases "a" and "b".) (a & b) If the cooler temperature is >45°F and the shellstock temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to another cooler. If the cooler temperature is >45°F and the shellstock temperature is >50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated to insure the product is safe. c) Wet stored shellstock subjected to water quality conditions that do not meet the requirements of the Shellfish Model Ordinance will be evaluated by VDH for final disposition.	Minimum weekly review of shellstock storage area records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock storage temperature record Thermometer calibration record Corrective action record Wet storage permit

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Example HACCP Plan Form - Reshipper

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Reshipping of previously processed & packaged

_____ shellfish intended for fresh distribution

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Receiving	Shellfish may contain pathogens, marine biotoxins and toxic chemicals if received from growing waters closed to shellfish harvesting.	All shellstock or shucked shellfish must originate from a dealer who has identified the shellfish with a tag or label.	Shellfish tag or label	Visual check	Upon receipt of each shipment	Plant personnel as assigned	Reject any shellfish that are without an identifying tag or label.	Minimum weekly review of shellfish receiving records and corrective action records by a HACCP trained individual.	Receiving Record Corrective action record

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Shellstock Points of transfer/loading dock	Growth of pathogenic bacteria	Once under temperature control, shellstock not permitted to remain outside of refrigeration for more than 2 hours.	Time out of temperature control.	Record duration of time shellstock outside of temperature control.	For every lot or pallet.	Plant personnel as assigned.	If the shellstock are out of temperature control for more than 2 hours then check internal temperature. If the internal temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to a cooler. If the shellstock temperature is >50°F, the product will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated by a HACCP trained individual to insure the product is safe.	Minimum weekly review of shellstock transfer records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock temperature control record Thermometer calibration record Corrective action record

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Example HACCP Plan Form - Shucker-Packer

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Hand shucking, packing and repacking

_____ shellfish for fresh distribution

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring (4) What	(5) How	(6) Frequency	(7) Who	(8) Corrective action	(9) Verification	(10) Records
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Shellstock Points of transfer/loading dock	Growth of pathogenic bacteria	Once under temperature control, shellstock not permitted to remain outside of refrigeration for more than 2 hours at loading dock.	Time out of temperature control.	Record duration of time shellstock outside of temperature control.	For every lot or pallet.	Plant personnel as assigned.	If the shellstock are out of temperature control for more than 2 hours then check internal temperature. If the internal temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to a cooler. If the shellstock temperature is >50°F, the product will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated by a HACCP trained individual to insure the product is safe.	Minimum weekly review of shellstock transfer records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock temperature control record Thermometer calibration record Corrective action record

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Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Hand shucking, packing and repacking

_____ shellfish for fresh distribution

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring (4) What	Monitoring (5) How	Monitoring (6) Frequency	Monitoring (7) Who	(8) Corrective action	(9) Verification	(10) Records
Shucking	Growth of pathogenic bacteria	1) For shellstock that has not been refrigerated prior to shucking, the time processing begins to the time shucked meats are chilled to an internal temperature of 45°F (7.2°C) shall not exceed 3 hours. 2) For shellstock that has been refrigerated prior to shucking, the time shellfish are removed from the shellstock cooler to the time shucked meats are chilled to an internal temperature of 45°F (7.2°C) shall not exceed 6 hours. 3) For heat shocked shellstock the shucked shellfish meats shall be cooled to 45°F (7.2°C) or less within 2 hours after the heat shock process.	1 & 2) Elapsed time shellfish remain out of temperature control during processing until chilled to an internal temperature of 45°F (7.2°C). Temperature of shellfish at time of packing. 3) For heat shocked shellfish, elapsed time from heat shock process until shellfish are at 45°F (7.2°C) or less.	1) Record time that shucking begins and record the time when the last shucked product is chilled to an internal temperature of 45°F (7.2°C) or less. Record temperature of a representative sample of shellfish at time of packing. 2) Record time that shellstock are initially removed from the cooler for shucking and record the time when the last shucked product is chilled to an internal temperature of 45°F (7.2°C) or less. Record temperature of a representative sample of shellfish at time of packing. 3) Record elapsed time from heat shock process to time heat shocked shellfish are at 45°F (7.2°C) or less.	1) At least every 3 hours when shucking unrefrigerated shellstock 2) At least every 6 hours when shucking refrigerated shellstock.	Plant personnel as assigned	Cool shellfish to 45°F as quickly as possible and implement temperature control. Shucked shellfish meats out of temperature control for more than 6 hours during processing will be held and evaluated by, at a minimum, a HACCP trained individual for final disposition.	Minimum weekly review of shellfish weighing/ packing records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellfish weighing/ packing record Thermometer calibration record Corrective action record

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shucker-Packer

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Hand shucking, packing and repacking shellfish for fresh distribution

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Repacking Shucked shellfish	Growth of pathogenic bacteria	Shucked shellfish shall be maintained at an internal temperature of 45° F (7.2° C) or less. Frozen shellfish thawed for repacking shall not exceed an internal temperature of 45° F (7.2° C).	Temperature of shucked shellfish during processing.	Check temperature of representative sample of shellfish.	1) At least every 2 hours during processing; or 2) At the end of the repacking operation if less than 2 hours.	Plant personnel as assigned	1) Add ice to containers or vessels of 128 oz. (1 gallon) or greater containing the shellfish to be repacked. 2) Chill containers of less than 128 oz. (1 gallon) as rapidly as possible with ice. 3) Hold shellfish aside and evaluate by, at a minimum, a HACCP trained individual.	Minimum weekly review of shellfish repacking records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shucked shellfish repacking record Thermometer calibration record Corrective action record

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shucker-Packer

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Hand shucking, packing and repacking shellfish for fresh distribution

_____

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Shucked meat storage	Growth of pathogenic bacteria	Shucked and packed shellfish must be stored in: a) Ice or b) Under refrigeration at a temperature of 45°F (7.2°C) or less.	a) Presence of adequate ice or b) Storage area temperatures.	a) Visual check for presence of adequate ice or b) Recording storage area temperatures.	a) Minimum of 1 time per day for iced product or b) Minimum of 2 times per day for refrigerated product.	Plant personnel as assigned.	If iced shellfish are without adequate ice, or if shellfish are not iced and cooler temp. is above 45°F, take temperature of shellfish. Shucked shellfish with a temperature greater than 45°F are iced and held for evaluation by, at a minimum, a HACCP trained individual for final disposition. Restore temperature control.	Minimum weekly review of shucked meat storage records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shucked meat storage record Thermometer calibration record Corrective action record

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shellstock Shipper

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Washing, grading and packaging of whole, live shellfish in the shell

_____

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Receiving Shellstock	Shellfish may contain pathogens, marine biotoxins and toxic chemicals if received from growing waters closed to shellfish harvesting.	Receive only shellstock: 1) Obtained from licensed harvester or aquaculturist who has; a) harvested the shellstock from approved areas as indicated by the tag and b) identified the shellstock with a tag or transaction record -or- 2) Obtained from a dealer who has identified the shellstock with a tag or transaction record.	Shellstock tag or transaction record	Visual check	Upon receipt of each shipment	Plant personnel as assigned	Reject any shellstock that are without an identifying tag or transaction record.	Minimum weekly review of shellstock receiving records and corrective action records by a HACCP trained individual.	Shellstock Receiving Record Corrective action record

Signature of Company Official:_____ Date:_____

ver. 3/20/01

Example HACCP Plan Form - Shellstock Shipper

Firm Name: _____

Firm Address: _____

_____

Product Type: Oyster, Hard clam

Process Method: Washing, grading and packaging of whole, live shellfish in the shell

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Shellstock Points of transfer/loading dock	Growth of pathogenic bacteria	Once under temperature control, shellstock not permitted to remain outside of refrigeration for more than 2 hours at loading dock.	Time out of temperature control.	Record duration of time shellstock outside of temperature control.	For every lot or pallet.	Plant personnel as assigned.	If the shellstock are out of temperature control for more than 2 hours then check internal temperature. If the internal temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to a cooler. If the shellstock temperature is >50°F, the product will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated by a HACCP trained individual to insure the product is safe.	Minimum weekly review of shellstock transfer records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock temperature control record Thermometer calibration record Corrective action record

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shellstock Shipper

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Washing, grading and packaging of whole, live shellfish in the shell

_____

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Shellstock Washing, grading and packing	Growth of pathogenic bacteria	Once under temperature control, shellstock not permitted to remain outside of refrigeration for more than 2 hours while processing.	Time out of temperature control.	Record duration of time shellstock outside of temperature control.	For every lot or pallet.	Plant personnel as assigned.	If the shellstock are out of temperature control for more than 2 hours then check internal temperature. If the internal temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to a cooler. If the shellstock temperature is >50°F, the product will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated by a HACCP trained individual to insure the product is safe.	Minimum weekly review of shellstock transfer records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock temperature control record Thermometer calibration record Corrective action record

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shellstock Shipper

Firm Name: _____

Firm Address: _____

_____

Product Type: Oyster, Hard clam

Process Method: Washing, grading and packaging of whole, live shellfish in the shell

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring (4) What	Monitoring (5) How	Monitoring (6) Frequency	Monitoring (7) Who	(8) Corrective action	(9) Verification	(10) Records
Shellstock storage	Growth of pathogenic bacteria	Shellstock must be: a) Iced; or b) Stored in a storage area or conveyance maintained at 45°F (7.2°C) or less; or c) Placed in an approved wet storage area.	a) Presence of ice; or b) Shellstock cooler temperature; or c) Wet storage area water quality	a) Visual check for presence of adequate ice; or b) Record shellstock cooler temperatures; or c) Wet storage permit	a & b) Minimum of 2 times per day	Plant personnel as assigned	(Note: If monitoring frequency is less than 3 times/day, the following corrective actions must be listed for cases "a" and "b".) (a & b) If the cooler temperature is >45°F and the shellstock temperature is between 45°F - 50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F and moved to another cooler. If the cooler temperature is >45°F and the shellstock temperature is >50°F, the shellstock will be iced or chilled as rapidly as practicable to bring the internal temperature to 45°F, isolated and evaluated to insure the product is safe. c) Wet stored shellstock subjected to water quality conditions that do not meet the requirements of the Shellfish Model Ordinance will be evaluated by VDH for final disposition.	Minimum weekly review of shellstock storage area records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shellstock storage temperature record Thermometer calibration record Corrective action record Wet storage permit

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shellstock Shipper (boat certification)

Firm Name: _____ Product Type: Shellstock oysters and hard clams

Firm Address: _____ Process Method: Shellstock washed, bagged or boxed and tagged at harvest site; shipped within 20 hours of harvest; no storage

_____

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Harvesting	Shellfish may contain pathogens, marine biotoxins and toxic chemicals if harvested from growing waters closed to shellfish harvesting.	Ship only shellfish: a) harvested under this boat certification b) harvested from approved areas c) identified with shellstock tag.	Shellstock tag and shellstock shipping record	a) On shellstock tag: record type of shellfish, harvest location, and harvest date. b) On shipping record: indicate type of shellfish, quantity, harvest location, harvest date and buyer.	Tag each shellstock container when packed. Daily for shipping record	Harvester	Tag any shellstock that are missing the identifying tag.	Minimum weekly review of shellstock shipping records by a HACCP trained individual.	Shellstock shipping record

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shellstock Shipper (shucked product)

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Reship shucked shellfish

_____ Intended for fresh distribution

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring (4) What	(5) How	(6) Frequency	(7) Who	(8) Corrective action	(9) Verification	(10) Records
Receiving	Shellfish may contain pathogens, marine biotoxins and toxic chemicals if received from growing waters closed to shellfish harvesting.	Shucked shellfish must originate from a dealer who has identified the shellfish with a label.	Shellfish label	Visual check	Upon receipt of each shipment	Plant personnel as assigned	Reject any shellfish that are without an identifying label.	Minimum weekly review of shellfish receiving records and corrective actions by a HACCP trained individual.	Receiving Record Corrective action record

Signature of Company Official: _____ Date: _____

ver. 3/20/01

Example HACCP Plan Form - Shellstock Shipper (shucked product)

Firm Name: _____ Product Type: Oyster, Hard clam

Firm Address: _____ Process Method: Reship shucked shellfish

_____ Intended for fresh distribution

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring (4) What	(5) How	(6) Frequency	(7) Who	(8) Corrective action	(9) Verification	(10) Records
Shucked meat storage	Growth of pathogenic bacteria	Shucked and packed shellfish must be stored in: a) Ice or b) Under refrigeration at a temperature of 45°F (7.2°C) or less.	a) Presence of adequate ice or b) Storage area temperatures.	a) Visual check for presence of adequate ice or b) Recording storage area temperatures.	a) Minimum of 1 time per day for iced product or b) Minimum of 2 times per day for refrigerated product.	Plant personnel as assigned.	If iced shellfish are without adequate ice, or if shellfish are not iced and cooler temperature is above 45°F, take temperature of shellfish. Shucked shellfish with a temperature greater than 45°F are iced and held for evaluation by, at a minimum, a HACCP trained individual for final disposition. Restore temperature control.	Minimum weekly review of shucked meat storage records and corrective action records by a HACCP trained individual. Monthly calibrate thermometer against NIST certified thermometer or agitated ice slush; or Use NIST certified thermometer and check to ensure certification duration is still valid.	Shucked meat storage record Thermometer calibration record Corrective action record

Signature of Company Official: _____ Date: _____

ver. 3/20/01